DEC 2 3 2009

K093613

ESCALON VASCULAR ACCESS
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Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness for the VascuView TAP™ Ultrasound System is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and the Premarket Notification Procedures of 21 CFR; Part 807, Subpart E, Section 807.92 upon which the substantial equivalence (SE) determination is based.

Submitter's Name

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Date of Preparation

October 13, 2009

Device Trade Name

VascuView TAP™ Ultrasound System

Common Name(s)

Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Classification Name(s)

Ultrasonic Pulsed Echo Imaging System
FR Number: 892.1560
Product Code: 90-IYO

Diagnostic Ultrasound Transducer
FR Number: 892-1570
Product Code: 90-ITX

Ultrasonic Pulsed Doppler Imaging System
FR Number: 892-1550
Product Code: 90-IYN

Device Classification

Class II

Predicate Device(s)

SONOACE PICO Diagnostic Ultrasound System
510(k) Number: K061213
SE Clearance Date: May 16, 2006

Sonosite iLook 25 Personal Imaging Tool
510(k) Number: K033367
SE Clearance Date: November 5, 2003

VascuView TAP Device Description

The VascuView TAP Ultrasound System is a high-frequency ultrasonic imaging system intended to be used for assisted vascular access of veins and arteries, in addition to other vascular access applications such as the real-time viewing of peripheral vascular structures and their surrounding regions in order to provide guidance for the placement of needles and catheters within these structures. The system software runs on Windows XP Professional Operating System and utilizes features of the Windows interface to direct the operation of the system and maintain patient records; providing a user-friendly environment for clinical applications. The VascuView TAP System consists of the following components:

- *UL and TUV 60950 Approved Tablet PC with Integrated Outer Enclosure*
  A Kiosk tablet pc is provided with a UL approved Medical-grade power supply and Medical-grade power cord. The VascuView TAP ultrasound system consists of an integrated carrying handle, probe holder, cord wrap, table stand, and shock absorbent corner bumpers. The pc includes a large 12.1" TFT XGA LCD wide angle display which facilitates an intuitive touch screen control interface with clear-cut functionality and preset settings to ameliorate image optimization. Additionally, the pc provides for the operation of the software, as well as the storage of archived images and video clips.

- *Ultrasound Beam-former PCB with 64-element Linear Array Probe*
  The handheld ultrasound probe Model #HL7.5/40/64D and beam-former PCB consists of a sixty-four element pulsed linear array capable of capturing both images and videos in four different modes of operation: B-Mode, Split Screen Dual B-Mode, Color Doppler (CFM), and B-Mode with Doppler (PWD). The probe is connected to the pc via the included SCSI cable and operates within a frequency range of 5MHz – 10MHz, which allows for the visualization of surface vessels at scan depths up to 9cm. The transducer material is made of a gold plated polymer membrane and a biocompatible nose cone sufficient for its use (Silicon).

- *VascuView TAP System Software*
  All features and controls of the system are provided for in the VascuView TAP software which comes pre-loaded onto the tablet pc. The software uses an icon-based interface whereby the user can select any of the primary functional screens at any time by clicking on an icon located on the screen, for that function. The software enables ultrasound image storage and display, measurement functions, enhancements, and printing. All parameters within the hard-coding of the VascuView TAP software program are fixed, therefore the user cannot make any adjustments to the operation of the transducer that will have an effect on the radiated field (i.e. center frequency, aperture, focus, field of view, sample rate, etc.)

The VascuView TAP Ultrasound System has been designed, as applicable to its features, to comply with the following product safety standards listed in the table below.

IEC Standard	• IEC 60601-1:2005 Medical Electrical Equipment: Part 1 – General Requirements for Safety • IEC 60601-1-1:2000 Medical Electrical Equipment Collateral Standard: Safety Requirements for Medical Electrical Systems • IEC 60601-1-2:2001 Medical Electrical Equipment Collateral Standard: Electromagnetic Compatibility • IEC 60601-1-4:1996 Medical Electrical Equipment Collateral Standard: Part 4: Safety Requirements for Programmable Electronic Medical Systems • IEC 60601-2-37:2004 Medical Electrical Equipment: Part 2 – Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring
EN Standard	• EN 61000-3-2:2000 Limits for Harmonic Current Emissions • EN 61000-3-3:1995 Electromagnetic Compatibility: Limitation of Voltage Fluctuation and Flicker in Low-Voltage Supply Systems with Rated Current Up to 16 Amps • EN 55011: 1998 (A1:1999) Group 1, Class A for Industrial, Scientific, and Medical (ISM) Equipment
CISPR Standard	• CISPR 11:2004 Group 1, Class A, for Industrial, Scientific, and Medical (ISM) Equipment: Radio Frequency Equipment Electromagnetic Disturbance Characteristics Limits and Methods of Measurement
ISO Standard	• ISO 14971:2007 Medical Devices – Applications of Risk Management to Medical Devices • ISO 13485:2003 Medical Devices Quality Management Systems – Requirements for Regulatory Purposes • ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing within a Risk Management Process • ISO 10993-5:2009 Biological Evaluation of Medical Devices: Part 5 – Tests for In Vitro Cytoxicity • ISO 10933-10:2002 Biological Evaluation of Medical Devices: Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity • ISO 10993-11:2006 Biological Evaluation of Medical Devices: Part 11 – Tests for Systemic Toxicity

Intended Use / Indications for Use

The VascuView TAP Ultrasound System with probe Model #HL.7.5/40/64D is intended for diagnostic imaging of the human body for the following clinical applications, as illustrated in the Diagnostic Indications for Use Form which can be found in Attachment 5A: Pediatric, Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Peripheral Vessels which include Intra-Venous and Peripherally-Inserted Central Catheters, as well as vascular structures and surrounding vascular regions such as nerve bundles and various structures for free hand placement of needles/catheters. The VascuView TAP Ultrasound System is not intended for fetal or ophthalmic applications.

Device Technology Characteristics and Comparison to Predicate Device(s)

The legally marketed predicate device(s) to which the VascuView TAP Ultrasound System is considered substantially equivalent through the 510(k) premarket notification process are the SONOACE PICO Diagnostic Ultrasound System cleared under K061213 and the SonoSite® iLook 25 Ultrasound System cleared under K033367.

Based on the Comparison with Predicate Devices as shown in the table illustrated in Section 6 of this 510(k) submission, as per the guidance of FDA Substantial Equivalence recommendations, the VascuView TAP Ultrasound System is deemed sufficient in the demonstration of substantial equivalence to both predicate devices. A summarization of the similarities and differences between the VascuView TAP and each of the proposed predicate devices is discussed below.

Summary for explanation of the Predicate Device(s) Technological Characteristics

Proprietary Device Name	SONOACE PICO Diagnostic Ultrasound System	SonoSite® iLook 25 Ultrasound System
Trade Name	SONOACE PICO Ultrasound System	iLook 25 Ultrasound System
510(k) Submitter/Holder	Medison, Co., Ltd.	SonoSite, Inc.
510(k) Number	K061213	K03367
Regulatory Class	Class II	Class II
Regulation Number	21 CFR 892.1550	21 CFR 892.1550
Classification Product Code	IYN	IYN

Similarities of the SONOACE PICO and the VascuView TAP include:

- Both systems are intended for Pediatric, Vascular, and Musculoskeletal applications.
- Both systems are mobile, software-controlled systems whose function is to acquire ultrasound data and to display the data in different imaging modes.
- Both systems are capable of displaying images in the following modes of operation: 2D B-Mode, Color Doppler (CFM), and B-Mode with Doppler (PWD).
- Both systems possess linear measurement capabilities.
- Both systems include a 64-element linear array probe design operating within a frequency range of 5MHz – 10MHz.
- Both systems have an LCD display
- Both systems include Cine review capabilities.
- Both systems transmit ultrasonic energy into patients, then perform post-processing of received echoes to generate on-screen display of anatomic structures within the body.
- Both systems allow for specialized measurements of structures.
- Both systems provide for on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms

Differences of the SONOACE PICO and the VascuView TAP include:

- The SONOACE PICO is a dedicated device, while the VascuView TAP system utilizes a tablet pc set up to launch immediately into the VascuView TAP software.
- The VascuView TAP provides for a larger screen to aid in visualization.
- The SONOACE PICO offers M-Mode Imaging, Tissue Harmonic Imaging, Trapezoidal Imaging, and freehand 3D imaging tools of which are not provided for in the Vascuview TAP.
- The SONOACE PICO indications for use includes: fetal applications, whereas the VascuView TAP is not.

Similarities of the SonoSite® iLook 25 Ultrasound System and the VascuView TAP include:

- Both systems are intended for Pediatric, Vascular, and Musculoskeletal (both conventional and superficial), and Peripheral Vessel applications.
- Both systems are highly portable, software-controlled systems whose function is to acquire ultrasound data and to display the data in different imaging modes.
- Both systems are capable of displaying images in the following modes of operation: 2D B-Mode, and Color Doppler (CFM) Mode.
- Both systems possess linear measurement capabilities which incorporate a linear array probe and beamformer (pulser and receiver) circuitry.
- Both systems provide controls for touch screen data input, menu, freeze, patient information, save and power.
- Both systems provide a power Doppler mode that displays different colors (red or blue) by determining directionality of blood flow within vessels which, given the anatomical location of the vessel and orientation of the ultrasound probe.
- Both systems assist the user in determining whether a vessel is a vein or artery by allowing for the observation of whether the vessel is pulsing (indicating an artery) or not (indicating a vein), in addition to anatomical location.
- Both systems include Cine review to retain images for frame-by-frame viewing.
- Both systems provide for system optimization presets and a crystal display with brightness and contrast controls.

Differences of the SonoSite® iLook 25 Ultrasound System and the VascuView TAP include:

- The SonoSite® iLook 25 is a dedicated device, while the VascuView TAP system utilizes a tablet pc set up to launch immediately into the VascuView TAP software.
- The VascuView TAP provides for a larger screen to aid in visualization; approximately 4x greater in viewing area.
- The SonoSite® iLook 25 is limited to an internal storage capacity of 74 images, while the VascuView TAP system has virtually unlimited storage (tens of thousands of images on tablet pc hard drive and ability to connect external hard drives if additional storage is required).
- The SonoSite® iLook 25 indications for use includes: fetal applications, whereas the VascuView TAP is not.

Non-Clinical Performance Data

The VascuView TAP will be assessed as verified as compliant with the requirements of several international safety standards, including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, and IEC 60601-2-37 (including acoustic output limits), and others. Additionally, the measurement accuracy of the VascuView TAP system was confirmed via a measurement validation test protocol (Attachment 8A Measurement Accuracy Validation Report) using an ATS model 539 phantom with 0.7 dB/cm-MHz attenuation. The software has been also been validated using a test protocol.

Clinical Performance Data

None submitted.

Conclusions from Non-Clinical (and Clinical) Data

Based upon the results of the data as summarized above, the VascuView TAP system has demonstrated that it is as safe, as effective, performs as well as or better than the predicate devices, and includes similar design characteristics and intended use. Furthermore, based on the comparison with the predicate devices as shown in the discussion above, as well as guidance provided by FDA 510(k) Substantial Equivalence Decision-Making Process Flowchart, the Escalon Vascular Access VascuView TAP ultrasound system is deemed to be substantially equivalent to the proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 23 2009

Escalon Medical Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K093613
Trade/Device Name: VU65000 – VascuView TAP Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 16, 2009
Received: December 17, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the VU65000 – VascuView TAP Ultrasound System, as described in your premarket notification:

Transducer Model Number

HL7.5/40/64D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K093613

Device Name: VascuView TAP Ultrasound System

Indications For Use: The VascuView TAP ultrasound system provides ultrasound imaging of peripheral vascular structures in order to provide for ultrasound guidance for placement of needles and catheters in these structures. The VascuView TAP is also used for ultrasound imaging of vascular structures and surrounding regions of the vascular such as nerve bundles and various structures.

The VascuView TAP ultrasound system is not intended for fetal or ophthalmic applications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093613

Appendix G: Diagnostic Ultrasound Indications For Use Form

System: VU65000 – VascuView TAP Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Modes of Operations						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Opthalmic	Opthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	Note [1]	
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N		N		N	Note [1]	
	Musculo-skeletal **(Superficial)**	N		N		N	Note [1]	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel Note [2]	N		N		N	Note [1]	
	Other (Specify) Note [3]	N		N		N	Note [1]	

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Example of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging for prescription use.

Notes:

[1] B+PW, B+Color Doppler
[2] Includes Intra-Venous, Peripherally-Inserted Central Catheters
[3] Imaging of vascular structures and surrounding regions of the vascular such as nerve bundles and various structures for free hand placement of needles/catheters.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093613

Appendix G: Diagnostic Ultrasound Indications For Use Form

System: VU65000 – VascuView TAP Ultrasound System
Transducer: Probe Model #HL7.5/40/64D

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Modes of Operations						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Opthalmic	Opthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N		N		N	Note [1]	
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N		N		N	Note [1]	
	Musculo-skeletal **(Superficial)**	N		N		N	Note [1]	
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel Note [2]	N		N		N	Note [1]	
	Other (Specify) Note [3]	N		N		N	Note [1]	

N = new indication; P = previously cleared by FDA; E = added under this appendix
*Example of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging for prescription use.

Notes:

[1] B+PW, B+Color Doppler
[2] Includes Intra-Venous, Peripherally-Inserted Central Catheters
[3] Imaging of vascular structures and surrounding regions of the vascular such as nerve bundles and various structures for free hand placement of needles/catheters.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
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